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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,534	06/01/2006	Christopher John Burns	415852000200	6170

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EXAMINER	
WILLIS, DOUGLAS M	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
02/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,534	BURNS ET AL.	
	Examiner	Art Unit	
	DOUGLAS M. WILLIS	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-12 and 14-28* is/are pending in the application.

4a) Of the above claim(s) *15-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-12,14 and 21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09-29-06; 09-13-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 10-12 and 14-28 are pending in the current application. According to the *Claim Amendments*, filed October 30, 2009, claims 10-12 and 14-20 were amended, claims 1-9 and 13 were cancelled and claims 21-28 were added. This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/AU2004/001689, filed December 3, 2004, which claims priority under 35 U.S.C. § 119(a-d) to AU 2003906680, filed December 3, 2003.

Status of Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. § 119(a-d) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 119(a-d) as follows:

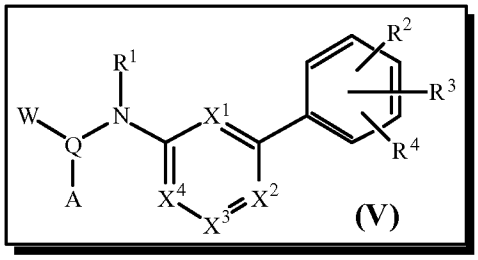
The later-filed application must be an application for a patent, for an invention which is also disclosed in the prior application (the foreign application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. § 112. {See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994)}.

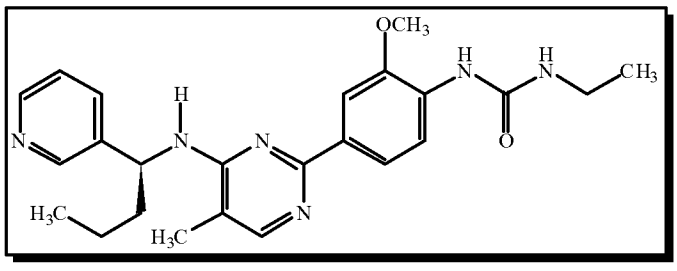
The disclosure of the prior-filed application, AU 2003906680, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. § 112 for one or more claims of this application for the following reason: the specification in the instant application has been amended with respect to the scope of formula (V), which now discloses amended definitions for R^2, and is no longer coextensive with that of AU 2003906680.

Consequently, since the specification of AU 2003906680 lacks adequate support or enablement for one or more claims of the elected invention of Group II, as defined below in *Restrictions / Election of Species*, and in the manner provided by the first paragraph of 35 U.S.C. § 112, the first Office action on the merits of all relevant claims drawn to Group II will be prosecuted according to the earliest effective filing date afforded this invention, which is that of the parent application, filed December 3, 2004.

Restrictions / Election of Species

Applicant's provisional election of the following, with traverse, in the reply filed on October 30, 2009, is acknowledged: a) Group II - claims 10-12, 14 and 21-28; and b) substituted pyrimidine of formula (V) - p. 48, example 18, shown right below, and hereafter referred to as (*S*)-1-ethyl-3-(2-methoxy-4-(5-methyl-4-((1-(pyridin-3-yl)butyl)amino)pyrimidin-2-yl)phenyl)urea, where $\mathbf{X^1}$ = **-N-**; $\mathbf{X^2}$ = **-N-**; $\mathbf{X^3}$ = **-C**Y-, wherein Y = -H; $\mathbf{X^4}$ = **-C**Y-, wherein Y = $-CH_3$; Q = -CH-; W = $-CH_2CH_2CH_3$; A = -pyridin-3-yl; R^1 = -H; R^2 = $-NR^{10}CONR^8R^9$, wherein R^8 = -H, R^9 = $-CH_2CH_3$ and R^{10} = -H; R^3 = $-OCH_3$; and R^4 = -H. Claims 10, 12, 14 and 22-28 read on the elected species. Affirmation of this election must be made by applicant in replying to this Office action.





Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse. See MPEP

§ 818.03(a).

The requirement is still deemed proper and is therefore made FINAL.

Claims 15-20 were withdrawn from further consideration, pursuant to 37 CFR 1.142(b), as being drawn to a nonelected or cancelled invention, there being no allowable generic or linking claim.

Thus, a first Office action and prosecution on the merits of claims 10-12, 14 and 21-28 is contained within.

Specification Objection - Title

Applicant is reminded of the proper content of the title of the invention.

The title of the invention should be brief, but technically accurate and descriptive, preferably from two to seven words. See 37 CFR 1.72(a) and MPEP § 606.

The title of the invention is not technically accurate and descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. In the revised title, the examiner suggests identifying the substituted pyrimidines of the formula (V).

Claim Objections

Claim 23 is objected to because of the following informalities: *...wherein* R^8, R^9 *and* R^{12} *are as defined in claim 10* appears redundant and should be omitted, since, the claim depends from claim 10. Appropriate correction is required.

Claim 24 is objected to because of the following informalities: a) *chosen* should be replaced with *selected*, with respect to the *substituents for A*; b) *...wherein* R^{18} *and* R^{19} *are as defined in claim 10* appears redundant and should be omitted, since, the claim indirectly depends

from claim 10; and c) *...wherein R^{22} and R^{23} are as defined in claim 10* appears redundant and should be omitted, since, the claim indirectly depends from claim 10. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description - Substituted pyrimidines of the formula (V)

Claims 10, 14, 23 and 26 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the proviso with respect to the substituted pyrimidines of the formula (V), wherein *...when W is absent*, lacks adequate support within the specification, as filed. The specification, on pages 18-19, discloses generic substituted pyrimidines of the formula (V), which fail to expressly include substituted pyrimidinnes wherein *W is absent or a single bond.* Consequently, one of ordinary skill in the art, at the time this application was filed, may neither be reasonably apprised of the scope of the instantly recited substituted pyrimidines of the formula (V), nor recognize that the inventor was in possession of the instantly recited substituted pyrimidines of the formula (V), in view of the original disclosure of the application.

Applicant should note that under 35 U.S.C. § 132 and § 251, the proscription against the introduction of new matter in a patent application serves to prevent an applicant from adding

information that goes beyond the subject matter originally filed. {See *In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981); and MPEP § 2163.06-2183.07}.

Moreover, applicant should further note that in order to comply with the written description requirement of 35 U.S.C. § 112, first paragraph, each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure. When an explicit limitation in a claim *is not present in the written description whose benefit is sought, it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation.* {See *Hyatt v. Boone*, 146 F.3d 1348, 1353, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998); and *In re Wright*, 866 F.2d 422, 425, 9 USPQ2d 1649, 1651 (Fed. Cir. 1989)}. Consequently, new or amended claims, which introduce elements or limitations which are not supported by the as-filed disclosure, violate the written description requirement. {See *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971); and *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972)}. Furthermore, when filing an amendment, applicant should show support in the original disclosure for new or amended claims. See MPEP § 714.02 and § 2163.06.

The examiner suggests removing the proviso *…when W is absent*, with respect to *Q*, to overcome this rejection.

Scope of Enablement - Prodrugs, hydrates, solvates and crystal forms of substituted pyrimidines and compositions of the formula (V)

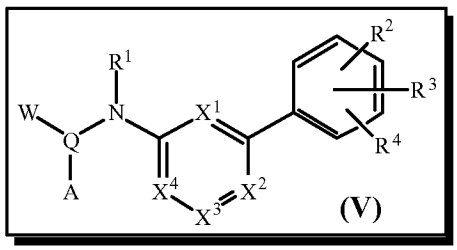
Claims 10-12, 14 and 21-28 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for substituted pyrimidines and compositions of the formula (V), does not reasonably provide enablement for *prodrugs*, *hydrates*, *solvates* and/or

crystal forms of substituted pyrimidines and compositions of the formula (V). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. *Prodrugs*, *hydrates*, *solvates* and/or *crystal forms* of substituted pyrimidines and compositions of the formula (V), as recited in claim 10-12 and 25, respectively, have not been adequately enabled in the specification to allow any person having ordinary skill in the art, at the time this invention was made, to make and/or use *prodrugs*, *hydrates*, *solvates* and/or *crystal forms* of substituted pyrimidines and compositions of the formula (V).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is *undue*. These factors include, but are not limited to: (a) breadth of the claims; (b) nature of the invention; (c) state of the prior art; (d) level of one of ordinary skill in the art; (e) level of predictability in the art; (f) amount of direction provided by the inventor; (g) existence of working examples; and (h) quantity of experimentation needed to make or use the invention based on the content of the disclosure. {See *Ex parte Forman* 230 USPQ 546 (Bd. Pat. App. & Inter. 1986); and *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988)}.

The above factors, regarding the present invention, are summarized as follows:

(a) *Breadth of the claims* - the breadth of the claims includes all of the tens of thousands of substituted pyrimidines and compositions of the formula (V), shown right, as well as the myriad of potential *prodrugs*, *hydrates*, *solvates* and/or *crystal forms* formulated from these substituted pyrimidines and compositions of the formula (V), respectively;



(V)

(b) *Nature of the invention* - the nature of the invention is evaluation of *prodrugs*,

hydrates, *solvates* and/or *crystal forms* of substituted pyrimidines and compositions of the formula (V) and the pharmacokinetic behavior of these substances in the human body as tubulin inhibitors;

(c) *State of the prior art* - *Nature Reviews: Drug Discovery* offers a snapshot of the state of the drug development art. Herein, drug development is stated to follow the widely accepted Ehrlich model which includes: 1) development of a broad synthetic organic chemistry program; 2) subsequent testing of compounds in an appropriate laboratory model for the disease to be treated; and 3) screening of compounds with low toxicity in prospective clinical trials (Jordan, V. C. *Nature Reviews: Drug Discovery,* 2, **2003**, 205). Moreover, *WO 03/031406*, provides a synthesis of the instantly recited substituted pyrimidines of the formula (V) {Ding, et al. *WO 03/031406*, **2003**};

(d) *Level of one of ordinary skill in the art* - the artisans synthesizing applicant's *prodrugs*, *hydrates*, *solvates* and/or *crystal forms* of substituted pyrimidines and compositions of the formula (V), would be a collaborative team of synthetic chemists and/or health practitioners, possessing commensurate degree level and/or skill in the art, as well as several years of professional experience;

(e) *Level of predictability in the art* - Synthetic organic chemistry is quite unpredictable (See *In re Marzocchi and Horton* 169 USPQ at 367 ¶ 3). Similarly, it is unclear based on the combination of the instant specification and Ding, et al. in *WO 03/031406*, whether the full scope of the instantly recited substituted pyrimidines of the formula (V) is enabled. Moreover, the following excerpt is taken from Vippagunta, et al. with respect to the synthesis of *hydrates* and *solvates* of substituted pyrimidines and compositions of the formula (V) {Vippagunta, et al. *Advanced Drug Delivery Reviews*, 48, **2001**, 18}:

Predicting the formation of solvates or hydrates of a compound and the number of molecules of water or solvent incorporated into the crystal lattice of a compound is complex and difficult. Each solid compound responds uniquely to the possible formation of solvates or hydrates and hence generalizations cannot be made for a series of related compounds. Certain molecular shapes and features favor the formation of crystals without solvent; these compounds tend to be stabilized by efficient packing of molecules in the crystal lattice, whereas other crystal forms are more stable in the presence of water and/or solvents. There may be too many possibilities so that no computer programs are currently available for predicting the crystal structures of hydrates and solvates.

Similarly, the following excerpt is taken from Chawla, et al. with respect to the synthesis of *crystal forms (polymorphs)* of substituted pyrimidines and compositions of the formula (V) {Chawla, et al. *Curr. Res. & Info. Pharm. Sci.* (*CRIPS)*, 5, *1*, **2004**, 9-12}:

Polymorphism is the ability of a substance to exist in two or more crystalline phases that have different arrangement and/or conformation of molecules in the crystal lattice. However, they share a common form once they are in the solution phase. It can significantly affect the physiochemical, formulation and processing parameters, as well as the shelf life (stability) of the drug substance and excipients.

Polymorphism has contributed significant variability in product performance in pharmaceutical, chemical and food industry and continues to pose a challenge to pharmaceutical scientists in producing drugs of consistent quality. An inadvertent production of the 'wrong' polymorph at the crystallization stage or any transformations of one form to another during dosage form processing, storage and scale-up can result in pharmaceutical dosage forms which are either ineffective or toxic.

Finally, the following excerpt is taken from Burger's with respect to the synthesis of *prodrugs* of substituted pyrimidines and compositions of the formula (V) {Wolff, Manfred E., Ed. *Burger's Medicinal Chemistry and Drug Discovery - Fifth Edition,* New York: John Wiley & Sons, **1996**, vol. 1, 975-976}:

The design of prodrugs in a rational manner requires that the underlying causes which necessitate or stimulate the use of the prodrug approach be defined and clearly understood. It may then be possible to identify the means by which the difficulties can be overcome. The rational design of the prodrug can thus be divided into three basic steps: (1) identification of the drug delivery problem; (2) identification of the physiochemical properties required for optimal delivery; and (3) selection of a prodrug derivative that has the proper physiochemical properties and that will be cleaved in the desired biological compartment.

The difficulty of extrapolating data from animal to humans encountered during toxicokinetic and toxicologic studies with drugs is amplified with prodrugs, since not only metabolism of the active moiety might differ, but also its availability from the prodrug. As a matter of fact, there is presently no published rational for the conduct of animal and human pharmacokinetic programs during prodrug research and development.

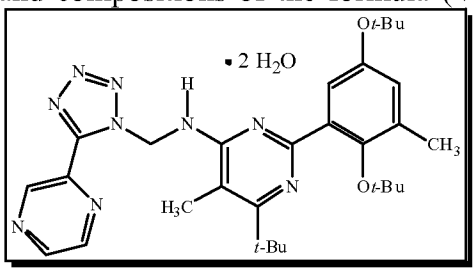
(f) *Amount of direction provided by the inventor* - the application is negligent regarding direction with respect to making and/or using *prodrugs*, *hydrates*, *solvates* and *crystal forms* of substituted pyrimidines and compositions of the formula (V);

(g) *Existence of working examples* - applicant has provided sufficient guidance to make and/or use substituted pyrimidines and compositions of the formula (V); however, the disclosure is insufficient to allow extrapolation of the limited examples to enable the scope of the tens of thousands of *prodrugs*, *hydrates*, *solvates* and/or *crystal forms* of substituted pyrimidines and compositions of the formula (V). The specification lacks working examples of *prodrugs*, *hydrates*, *solvates* and/or *crystal*

forms of substituted pyrimidines and compositions of the formula (V).

Within the specification, *specific operative embodiments or examples of the invention must be set forth. Examples and description should be of sufficient scope as to justify the scope of the claims. Markush claims must be provided with support in the disclosure for each member of the Markush group. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula.* See MPEP § 608.01(p).

(h) *Quantity of experimentation needed to make or use the invention based on the content of the disclosure* - predicting whether a *prodrug*, *hydrate*, *solvate* and/or *crystal form* of a recited compound is in fact one that produces a desired physiological effect at a therapeutic concentration and with useful kinetics, is filled with experimental uncertainty, and without proper guidance, would involve a substantial amount of experimentation (Jordan, V. C. *Nature Reviews: Drug Discovery,* 2, **2003**, 205-213). Similarly, the specification, as originally filed, including the references incorporated therein, fails to provide the necessary support required by 35 U.S.C. § 112, first paragraph, to enable the full scope of the instantly recited *prodrugs*, *hydrates*, *solvates* and/or *crystal forms* of substituted pyrimidines and compositions of the formula (V). Thus, it is unclear, based on the guidance provided by the specification, whether a *hydrate* of a substituted pyrimidine of the formula (V), such as 6-(*tert*-butyl)-2-(2,5-di-*tert*-butoxy-3-methylphenyl)-5-methyl-*N*-((5-(pyrazin-2-yl)-1*H*-tetrazol-1-yl)methyl)pyrimidin-4-amine dihydrate, shown to the left, is either synthetically feasible or possesses utility in the human body as a tubulin inhibitor.



A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. {See *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)}.

The determination that *undue experimentation* would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. (See *In re Wands,* 858 F.2d at

737, 8 USPQ2d at 1404). These factual considerations are discussed comprehensively in MPEP § 2164.08 (scope or breadth of the claims), § 2164.05(a) (nature of the invention and state of the prior art), § 2164.05(b) (level of one of ordinary skill), § 2164.03 (level of predictability in the art and amount of direction provided by the inventor), § 2164.02 (the existence of working examples) and § 2164.06 (quantity of experimentation needed to make or use the invention based on the content of the disclosure).

Based on a preponderance of the evidence presented herein, the conclusion that applicant is insufficiently enabled for making and/or using *prodrugs*, *hydrates*, *solvates* and/or *crystal forms* of substituted pyrimidines and compositions of the formula (V), is clearly justified.

Claim Rejections - 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 14, 23, 24, 26 and 27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase *optionally substituted 3-8 membered ring*, in claims 10 and 24, respectively, is a relative phrase which renders the claims indefinite. The phrase *optionally substituted 3-8 membered ring* is not defined by the claims, the specification does not provide an adequate standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification fails to adequately define the phrase *optionally substituted*, with respect to *3-8 membered ring*. Consequently, the substituted pyrimidines and compositions of the formula (V) have been rendered indefinite by

the use of the phrase *optionally substituted 3-8 membered ring*.

The examiner suggests removal of the phrase *optionally substituted*, with respect to *3-8 membered ring* and providing discrete substituents for each occurrence of *optionally substituted 3-8 membered ring*, to overcome this rejection.

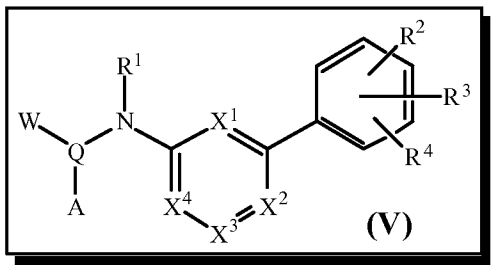
Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ding, et al. in WO 03/031406.

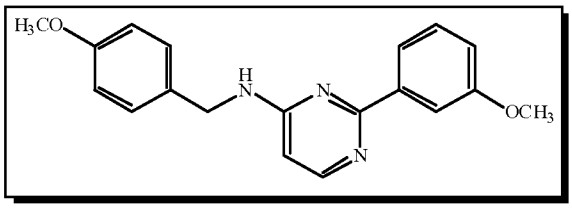
The instant application recites substituted pyrimidines and compositions of the formula



(V)

(V), shown to the left, where X^1 = -N-; X^2 = -N-; X^3 = -CY-, wherein Y = -H; X^4 = -CY-, wherein Y = -H; Q = -C_{1-4}alkyl-; W = -H; A = -aryl, substituted with *p*-OC_{1-4}alkyl; R^1 = -H; R^2 = -OC_{1-6}alkyl; R^3 = -H; and R^4 = -H, as tubulin inhibitors.

Ding, et al. (WO 03/031406), as provided in the file and cited in the IDS, teaches substituted pyrimidines and compositions of the formula (V), shown to the right, where X^1 = -N-; X^2 = -N-; X^3 = -CY-, wherein Y = -H; X^4 = -CY-,



wherein Y = -H; Q = -CH-; W = -H; A = -phenyl, substituted with *p*-OCH_3; R^1 = -H; R^2 = -OCH_3; R^3 = -H; and R^4 = -H, as kinase inhibitor scaffolds {p. 42, Table 2, entry 1; and pharmaceutical compositions - p. 34, ¶[0132]}.

Furthermore, although not explicitly discussed herein, applicant is advised to note that this reference contains additional species that may anticipate the instantly recited substituted pyrimidines of the formula (V). Consequently, any amendments to the claims or arguments formulated to overcome rejections rendered under 35 U.S.C. § 102 should address this reference as a whole and should not be limited to the species discussed or disclosed explicitly herein.

Allowable Subject Matter

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DOUGLAS M. WILLIS, whose telephone number is 571-270-5757. The examiner can normally be reached on Monday thru Thursday from 8:00-6:00 EST. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DOUGLAS M WILLIS/
Examiner, Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner, AU 1624